

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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IN RE: NEW ENGLAND COMPOUNDING	:	MDL No. 2419
PHARMACY, INC. PRODUCTS LIABILITY	:	Master Dkt. No.: 1:13-md-02419-FDS
LITIGATION	:	
-----	:	NON-PARTY INTERVENTIONAL
	:	SPINE & SPORTS MEDICINE, PC
	:	<u>OBJECTIONS TO SUBPOENA</u>
THIS DOCUMENT RELATES TO:	:	
	:	
ALL ACTIONS	:	
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Non-party Interventional Spine & Sports Medicine, PC ("ISSM"), by and through its attorneys, Golenbok Eiseman Assor Bell & Peskoe LLP, submits the following objections to the subpoena for a deposition and the production of documents, dated July 7, 2013 (the "Subpoena"¹), issued on behalf of Plaintiffs' Steering Committee ("PSC") by the law firm of Crandall & Katt in the above-captioned action ("MDL").

ISSM reserves the right to amend or supplement these objections as may be appropriate. These objections are not to be construed as an admission that ISSM has responsive documents or information in its possession, custody or control in response to any particular request or that such documents or information exist.

ISSM is filing these objections in the MDL pursuant to the Order on Central Enforcement of Subpoenas, dated June 21, 2013 ("Order on Central Enforcement"). The filing of these objections is not intended to be, and shall not be construed to be, a waiver or modification of the procedures set forth in Federal Rule of Civil Procedure ("FRCP") 45(c)(2)(B). As permitted by the Order on Central Enforcement, ISSM's counsel is making a limited appearance solely for

¹ A copy of the Subpoena and the cover letter from Crandall & Katt enclosing same are attached hereto as Exhibit A.

purposes of contesting the Subpoena, without consenting to the jurisdiction of this Court. ISSM specifically objects to the Subpoena on the ground that this Court lacks jurisdiction over ISSM, among other reasons.

PRELIMINARY STATEMENT

At all relevant times, ISSM was a one-physician practice located only in Connecticut. It is not a party to the MDL. ISSM has been in communication with each of its patients who may have been exposed to tainted product produced by defendant New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center ("NECC"), to ensure the safety of those patients. None of ISSM's patients has experienced any adverse reaction to any product supplied by NECC that was administered by ISSM. The incubation period identified by the Center for Disease Control has long expired with no symptoms reported by any of ISSM's patients. None of ISSM's patients is a plaintiff in the MDL or any related action.

PSC's Subpoena to ISSM is an improper attempt to obtain discovery from ISSM for the purpose of determining whether PSC may be able to assert claims against ISSM. PSC's purpose is revealed in the cover letter to ISSM enclosing the Subpoena, in which Patrick T. Fennell of Crandall & Katt states that "Lead Counsel and the PSC have designated me, Patrick T. Fennell of Crandall & Katt, to handle the day-to-day litigation of *claims against Interventional Spine & Sports Medicine, PC.*" (See Exhibit A at 2 (emphasis added).) There are no such claims against ISSM, but PSC admittedly is fishing for them. Indeed, the Subpoena seeks information about ISSM's insurance coverage, its organizational structure, and its communications with its patients. Such information could have no bearing on the liability of NECC or the other defendants in the MDL.

There is no provision in the FRCP for such a pre-claim subpoena to a non-party to obtain broad discovery to determine whether there may be a claim against that non-party (or to determine whether there may be insurance coverage for such hypothetical claim). Moreover, even if such a procedure were available, there are no grounds for a belief that there may be a claim against ISSM to justify such a subpoena and the burdens, expenses, and risks to patient privacy that the Subpoena would impose.

Accordingly, for these reasons and all of the reasons set forth below, ISSM objects to the Subpoena in its entirety and to each of the particular requests set forth therein.

GENERAL OBJECTIONS

The following General Objections apply to each of the Subpoena's document requests and the deposition request as if fully set forth in response thereto²:

1. ISSM objects to the Subpoena on the ground that PSC did not properly serve the Subpoena on ISSM. PSC sent the Subpoena by certified mail on July 12, 2013. No other form of delivery was made. PSC's service was invalid because FRCP 45(b)(1) requires personal service of a Subpoena. *See In re Pappas*, 214 B.R. 84, 85 (Bkrtcy. D. Conn. 1997); *Agran v. City of New York*, No. 95 Civ. 2170, 1997 WL 107452, at *1 (S.D.N.Y. Mar. 11, 1997) (service of subpoena by mail invalid because subpoena must be served by personal service); *In re Smith*, 126 F.R.D. 461, 462 (E.D.N.Y. 1989) (same); *see also James v. McKenna*, No. Civ.A. 02-0318, 203 WL 348921, at *2 (E.D. La. Feb. 6, 2003) (service by certified mail invalid because "[t]here

² ISSM is aware, through its counsel's review of the docket, that, on July 17, 2013, PSC filed "Accommodations," purporting to limit the scope of certain subpoenas served by PSC. It is unclear whether PSC is proposing to limit the Subpoena to ISSM pursuant to the Accommodations. Moreover, even in its Accommodations, PSC states that it reserves "its right to later seek to obtain the documents originally requested." (*See* PSC's Consolidated Response to Subpoena Objections, dated July 17, 2013 ("Consolidated Response"), at 8 n.13.) Accordingly, ISSM responds herein to the Subpoena as issued, but these objections also apply to the Accommodations because the Accommodations do not cure any of the objections set forth herein.

is no provision for service of a subpoena on a non-party by certified mail”); *Terre Haute Warehousing Serv., Inc. v. Grinnell Fire Protection Sys. Co.*, 193 F.R.D. 561, 562-63 (S.D. Ind. 1999) (“Subpoena must be personally served; certified mail service is insufficient.”); *Smith v. Midland Brake, Inc.*, 162 F.R.D. 683, 686 (D. Kan. 1995) (“service of a subpoena may not be accomplished by mail”).

2. ISSM objects to the Subpoena for improper service on the additional ground that the Subpoena seeks ISSM’s deposition, but PSC failed to tender any witness fee or mileage fee as required for effective service under FRCP 45(b)(1). PSC’s failure to include any witness fee or mileage fee simultaneously with service of the Subpoena renders the Subpoena “invalid and unenforceable.” *Bristol Heights Assocs., LLC v. Chicago Title Ins. Co.*, No. 3:12CV01658 (JCH), 2013 WL 1342288, at *3 (D. Conn. Apr. 2, 2013).

3. ISSM objects to the Subpoena on the ground that it was not issued from the proper court. The Subpoena was issued from the United States District Court for the District of Massachusetts. However, it seeks ISSM’s deposition and the production of documents in Middlebury, Connecticut, which is in the District of Connecticut. Under FRCP 45(a)(2), a subpoena “must issue” from “the court for the district where the deposition is to be taken,” and, if documents are sought, “from the court for the district where the production or inspection is to be made.” Accordingly, any subpoena to ISSM, even if otherwise proper, must issue from the United States District Court for the District of Connecticut.

4. ISSM objects to the Subpoena on the ground that the United States District Court for the District of Massachusetts does not have jurisdiction over ISSM, which is located only in Connecticut. The transferee court in an MDL does not have authority to enforce a subpoena seeking the production of documents issued outside of the transferee court’s district. *See, e.g.*,

Visx, Inc. v. Nidek Co., 208 F.R.D. 615 (N.D. Cal. 2002) (holding that 28 U.S.C. 1407(b) “expands a transferee court’s discovery powers only to pretrial depositions”). In PSC’s Consolidated Response, PSC argues that the Court’s lack of jurisdiction is remedied because PSC has included a request for a record-keeper deposition with the subpoenas. (*See* PSC’s Consolidated Response at 13 n.30.) However, in the same Consolidated Response, PSC states that it is “forgo[ing] all noticed depositions.” (*Id.* at 2.) Even if the inclusion of a record-keeper deposition request was sufficient to create jurisdiction, PSC’s gamesmanship should not be countenanced. PSC should not be permitted to create jurisdiction by inserting a request for a record-keeper deposition in the Subpoena with no intention of pursuing, and an express withdrawal of, that deposition request.

5. ISSM objects to the Subpoena on the ground that PSC failed to include with the Subpoena a copy of the Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information, dated June 21, 2013 (“Order Granting Leave”), as required by the Order Granting Leave. PSC’s failure to comply with the Order Granting Leave is particularly flagrant and egregious because, prior to PSC’s issuance of the Subpoena to ISSM, other objectors expressly put PSC on notice of the Court’s order that subpoenas to non-parties include a copy of the Order Granting Leave (*see, e.g.*, Docket Nos. 244, 246), yet PSC still did not comply with the Court’s order when PSC served the Subpoena on ISSM.

6. ISSM objects to the Subpoena on the ground that it exceeds the limitations on discovery imposed by the Order Granting Leave, including, without limitation, because the Subpoena seeks documents outside of the January 2011 to November 2012 timeframe imposed

by the Order Granting Leave and seeks documents outside of the categories authorized in the Order Granting Leave.

7. ISSM objects to the Subpoena to the extent production of the requested documents or information violates the Health Insurance Portability and Accountability Act (“HIPAA”). ISSM also objects to the Subpoena on the ground that it seeks information protected by applicable Connecticut privacy and confidentiality laws, including, without limitation, Connecticut General Statute (“C.G.S.”) 52-146o. ISSM understands that the Court’s Order Granting Leave has established a procedure for the production of HIPAA-protected information to create a safe harbor under that statute. However, PSC’s Subpoena to ISSM exceeds the scope of discovery authorized under the Order Granting Leave, and thus it is unclear whether any production of such additional information would fall within the safe harbor. Additionally, ISSM is not aware of any exception or safe harbor for the production of information protected under Connecticut privacy and confidentiality laws such as C.G.S. 52-146o. Non-party ISSM should not be required to violate, or incur the risk of violating, HIPAA and state privacy and confidentiality laws, particularly given the lack of relevance and cumulative and duplicative nature of the information sought from ISSM.

8. ISSM objects to the Subpoena on the ground that it is vexatious and seeks the production of documents that are neither relevant to, nor reasonably calculated to lead to the discovery of, admissible evidence, and thereby imposes undue burden and expense on ISSM. ISSM is not a defendant in the MDL, and no patient treated at ISSM is a party in the MDL. No patient of ISSM has demonstrated any adverse reaction to any products from NECC administered by ISSM, and the incubation period identified by the CDC has long expired. Accordingly, the information sought by the Subpoena to ISSM, which includes the identification of ISSM’s

patients, ISSM's dealings with NECC, and ISSM's organizational and insurance information, has no bearing on the claims in the MDL. In PSC's Consolidated Response, it sets forth the following three purported reasons for the relevance of the information sought: "(1) to establish or bolster its liability case against NECC, (2) to understand the role clinics, doctors, and/or health care providers played in the unfolding of the NECC-related debacle (including whether they or others share any liability) and (3) for purposes of providing actual notice of the bar date to potential claimants." (PSC's Consolidated Response at 8.) PSC's first two purported grounds, for which PSC provides no elaboration, are too vague and speculative for PSC to meet its burden of demonstrating relevance of the information sought from ISSM, particularly because PSC admitted in its cover letter to ISSM that its true reason for issuing the Subpoena to ISSM was the speculative and hypothetical "litigation of claims against" ISSM. (*See* Exhibit A at 2.) That is not an appropriate ground for the Subpoena because there is no provision in the FRCP or other applicable rules for discovery prior to the assertion of a claim to determine whether one has a claim and, additionally, there is no basis to believe that there may be a claim against ISSM. Such a "fishing expedition" is not an appropriate basis for a third-party subpoena. PSC's third purported ground for relevance -- "providing actual notice of the bar date to potential claimants" -- also does not support issuance of the Subpoena to ISSM. First, ISSM understands that no procedure has been established yet for the notification of potential claimants. The Court may require health care providers to notify their patients directly, in which case there is no need for the production of patient-identifying information and the associated risks of violations of HIPAA and state privacy and confidentiality laws. Moreover, the relevant patient information can be obtained from government agencies. PSC admits that it is working with the CDC to gain access to such information. (PSC's Consolidated Response at 11.) ISSM should not be required to

incur the burden, expense, and risks of improper disclosure from producing this information in the MDL since such information will be duplicative of information that PSC admittedly is obtaining from other sources.

9. ISSM objects to the Subpoena because the information sought from it, a practice that had one physician at all relevant times and no patients with any adverse effects from any NECC product, will be wholly cumulative and/or duplicative of information that PSC can obtain from other sources. Indeed, ISSM states that it has served subpoenas on 85 clinics, doctors, and health care providers. (*See* PSC's Consolidated Response at 1.) Moreover, it is premature for PSC to seek discovery from ISSM to seek to "bolster its liability case against NECC" when PSC has not even sought NECC's documents or information. PSC argues that "[t]he bankruptcy stay prohibits the plaintiffs from serving any formal discovery requests on NECC." (PSC's Consolidated Response at 12.) However, the bankruptcy stay does not prohibit PSC from obtaining NECC's documents and information by serving a subpoena on NECC's bankruptcy trustee.³

10. ISSM objects to the Subpoena on the ground that it failed to allow reasonable time for ISSM to comply, particularly in light of the number and overbreadth of the Subpoena's requests. ISSM also objects to the time period provided for compliance on the ground that it is shorter than the time period that the Court granted to non-parties to respond to subpoenas in the

³ PSC argues that it is more appropriate for PSC to seek the requested discovery from non-parties than from NECC because seeking the information from NECC would "further deplete the limited resources it is endeavoring to retain for the benefit of victims." (PSC's Consolidated Response at 12.) That argument is without basis because NECC's trustee is going to need to review and organize NECC's documents and information in all events to administer the bankruptcy and respond to claims, so the incremental cost of producing responsive information to PSC would be minimal. Moreover, PSC's stated desire to benefit victims is an additional reason why ISSM should not be forced to incur the burden and expense of responding to PSC's Subpoena. ISSM is itself a victim in the NECC matter because, through no fault of its own, it has been forced to expend considerable time and resources responding to the NECC recall and ensuring the safety of its patients, and thus ISSM should not be forced to incur additional time and expense responding to PSC's frivolous Subpoena.

Order Granting Leave. ISSM also objects to the Subpoena's designation of the date for compliance as confusing and impossible to comply with because the cover page of the Subpoena sets one date for compliance while the accompanying Deposition Notice sets another date for compliance.

11. ISSM objects to the Subpoena on the ground that it purports to require the deposition and document production to take place at ISSM's premises, to which ISSM does not consent.

12. ISSM objects to the Subpoena on the ground that it seeks proprietary and competitive information of ISSM. ISSM understands that a Stipulated Protective Order Governing Confidentiality ("Confidentiality Order") has been entered. ISSM never agreed to the Confidentiality Order and was not given the opportunity to provide input with respect to the form of the Confidentiality Order. The Confidentiality Order does not provide adequate protection for the proprietary and competitive information of ISSM sought by the Subpoena. In particular, the Confidentiality Order authorizes disclosure to all parties. ISSM understands that parties include other health care providers and that PSC is seeking to name additional health care providers. ISSM's competitive information, such as information relating to the identities of ISSM's patients and suppliers and ISSM's organizational structure and employees should not be disclosed to other health care providers because they could improperly use such information to seek to gain a competitive advantage over ISSM, such as by soliciting ISSM's patients or personnel or benefiting from contacts or efficiencies developed by ISSM. ISSM's proprietary and competitive information, if required to be produced, should be subject, at a minimum, to an attorneys' eyes only designation. Additionally, ISSM is concerned about the production of confidential information, whether its patients' information or its own information, even subject to Court

orders governing confidentiality, because PSC already has demonstrated flippancy toward the Court's orders and applicable rules of procedure by repeatedly issuing subpoenas in violation of those orders and rules, even after having received numerous prior objections identifying PSC's non-compliance.

13. ISSM objects to the Subpoena on the grounds that its requests are vague, ambiguous and do not specify the information sought with sufficient particularity.

14. ISSM objects to the Subpoena to the extent it seeks information outside of ISSM's possession, custody or control.

15. ISSM objects to the Subpoena to the extent it seeks "any and all documents and/or ESI reflecting, and/or related in any way whatsoever to" a topic on the grounds that it is overbroad, fails to identify the information sought with sufficient particularity, seeks the production of information not reasonably calculated to lead to the discovery of admissible evidence, seeks the production of documents that are duplicative and/or cumulative, and imposes undue burden and expense.

16. ISSM objects to the Subpoena to the extent it seeks the production of documents that are protected from disclosure by the attorney-client privilege, work product protection and/or other similar protections. Such documents will not be produced. ISSM does not waive, and intends to preserve, any and all applicable privileges and protections. To the extent ISSM were required to produce any documents in response to the Subpoena, any inadvertent disclosure of privileged information shall not constitute a waiver, in whole or in part, of any otherwise valid claim of privilege or protection. Any failure to assert a privilege or protection as to one document shall not be deemed to constitute a waiver of the privilege or protection as to any other document so protected.

17. ISSM objects to the Subpoena to the extent it seeks the production of documents or information protected from disclosure under FRCP 45(d)(1)(D).

18. ISSM objects to the Subpoena to the extent it attempts to impose obligations beyond or inconsistent with those imposed by the Federal Rules of Civil Procedure, the Local Rules of the United States District Court for the District of Connecticut and/or the Local Rules of the United States District Court for the District of Massachusetts or other applicable rules.

19. ISSM objects to the Subpoena's request for a deposition, which seeks information about the storage, searching, retrieval, production and authenticity of documents sought from ISSM, because the Subpoena and the document requests therein are defective for reasons set forth herein such that no documents will be produced, and thus there is no basis for such record-keeper deposition testimony.

20. ISSM objects to the Subpoena's request for a deposition as unnecessary and/or premature because it seeks record-keeping information to establish the authenticity and potential admissibility of documents sought from ISSM, but it is unknown at this time whether PSC will seek to use or rely on any of the documents sought from ISSM, particularly because the documents sought from ISM are not relevant and are cumulative and/or duplicative of information sought from other sources.

21. ISSM objects to the Subpoena's request for a deposition on the ground that reasonable steps were not taken "to avoid imposing undue burden or expense" on ISSM pursuant to FRCP 45(c)(1) because the record-keeping information sought by the deposition can be obtained, if necessary and appropriate, by less burdensome and expensive means than a deposition.

SPECIFIC OBJECTIONS

Subject to, and without waiver of, ISSM's General Objections, ISSM objects to the specific document requests in the Subpoena as follows, incorporating by reference the General Objections in each response:

REQUEST FOR PRODUCTION NO. 1:

Any and all documents and/or electronically stored information ("ESI") reflecting, and/or related in any way whatsoever to, the procurement of methylprednisolone acetate ("MPA") and any other injectable steroid preparations from New England Compounding Pharmacy, Inc. ("NECP") during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of steroid preparation, the cost you paid for the steroid preparation, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased. Also including account information, prescriptions submitted to NECP, prescription order forms, NECP charges for MPA (before and after any discounts applied).

RESPONSE TO REQUEST FOR PRODUCTION NO. 1:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the time period of the request exceeds the time period for products covered by the recall. ISSM further objects to this request on the ground that

it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks information protected by HIPAA and/or state privacy and confidentiality laws, such as prescription information. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC, and/or its trustee and/or the CDC. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties. ISSM further objects to this request on the ground that it seeks information that is protected from disclosure by the attorney-client privilege, work product protection or other applicable protections, particularly to the extent it seeks “[a]ny and all documents and/or electronically stored information (‘ESI’) reflecting, and/or related in any way whatsoever to” the topics in the request, which would purport to include privileged and protected information relating to ISSM’s response to the NECC recall and inquiries from government agencies.

REQUEST FOR PRODUCTION NO. 2:

Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of MPA, or its generic or name-brand equivalent, from any producer, compounding facility or manufacturer other than NECP, since October 6, 2007, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of the product, the cost you paid for the product, applicable warranties, shelf life, expiration dates, requirements and instructions for shipment and/or storage, and the specific identity of the preparation being purchased.

RESPONSE TO REQUEST FOR PRODUCTION NO. 2:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, this request seeks information about the procurement of product from entities other than NECC that are not parties to the MDL, and the request purports to cover a period of over five-and-a-half years without basis. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks proprietary and competitive information of ISSM, including, without limitation, the identities of ISSM's suppliers and information about the products and quantities ordered by ISSM and the prices paid by ISSM, which information would not adequately be protected by the Confidentiality Order to which ISSM never agreed and was never afforded an opportunity to provide input.

REQUEST FOR PRODUCTION NO. 3:

Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of cardioplegic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of cardioplegic solution, the cost you paid for the cardioplegic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for cardioplegic solution (before and after any discounts applied).

RESPONSE TO REQUEST FOR PRODUCTION NO. 3:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the time period of the request exceeds the time period for products covered by the recall. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks information protected by HIPAA and/or state privacy and confidentiality laws, such as prescription information. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 4:

Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of ophthalmic solution from NECP during the two-year period immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of ophthalmic solution, the cost you paid for the ophthalmic solution, applicable warranties, shelf life, expiration dates, and requirements and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for ophthalmic solution (before and after any discounts applied).

RESPONSE TO REQUEST FOR PRODUCTION NO. 4:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the time period of the request exceeds the time period for products covered by the recall. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks information protected by HIPAA and/or state privacy and confidentiality laws, such as prescription information. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee and/or the CDC. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties. ISSM further objects to this request on the ground that it seeks information that is protected from disclosure by the attorney-client privilege, work product protection or other applicable protections, particularly to the extent it seeks "[a]ny and all documents and/or ESI reflecting, and/or related in any way whatsoever to" the topics in the request, which would purport to include privileged and protected information relating to ISSM's response to the NECC recall and inquiries from government agencies.

REQUEST FOR PRODUCTION NO. 5:

Any and all documents and/or ESI reflecting, and/or related in any way whatsoever to, the procurement of preservative-free saline solution from NECP during the two-year period

immediately preceding October 6, 2012, including without limitation of the foregoing, information reflecting dates of shipment and/or receipt, quantities of shipment, lot numbers and other identifying labels, sizes of containers of saline solution, the cost you paid for the saline solution, applicable warranties, shelf life, expiration dates, and requirement and instructions for shipment and/or storage. Also including prescriptions submitted to NECP, prescription order forms, NECP charges for preservative-free saline solution (before and after any discounts applied).

RESPONSE TO REQUEST FOR PRODUCTION NO. 5:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the time period of the request exceeds the time period for products covered by the recall. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks information protected by HIPAA and/or state privacy and confidentiality laws, such as prescription information. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 6:

Any and all documents and/or ESJ reflecting, and/or related to, the identification of each and every patient that was administered an NECP product during the two-year period immediately preceding October 6, 2012, including patient name, address, date of birth, identification of product administered, and date product was administered.

RESPONSE TO REQUEST FOR PRODUCTION NO. 6:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, the time period of the request exceeds the time period for products covered by the recall, and this request includes within its scope information about patients who received products that have never been identified as contaminated. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks information protected by HIPAA and/or state privacy and confidentiality laws. Such protected patient information should not be disclosed, particularly where this request is not limited to patients who may have received product identified as contaminated. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, the CDC. ISSM further objects to this request on the ground that it seeks information that is protected from disclosure by the attorney-client privilege, work product protection or other applicable protections, particularly to the extent it seeks "[a]ny and all documents and/or ESI reflecting,

and/or related in any way whatsoever to” the topics in the request, which would purport to include privileged and protected information relating to ISSM’s response to the NECC recall and inquiries from government agencies.

REQUEST FOR PRODUCTION NO. 7:

Any and all documents and/or ESI reflecting or containing communications (written or otherwise) between Interventional Spine & Sports Medicine, PC (“Healthcare Provider”), its employees, principals, partners, and/or agents, and NECP, its employees and/or agents, during the two-year period immediately preceding October 6, 2012, including, but not limited to, any complaints or adverse event reports made to NECP by the Healthcare Provider.

RESPONSE TO REQUEST FOR PRODUCTION NO. 7:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM’s patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the time period of the request exceeds the time period for products covered by the recall. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request to the extent it seeks information protected by HIPAA and/or state privacy and confidentiality laws. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee and/or the CDC. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 8:

Any and all documents and/or ESI reflecting or containing information obtained by the Healthcare Provider, its employees and/or agents, regarding NECP, including without limitation of the foregoing, NECP's qualifications, certifications or accreditations, or lack thereof, regulatory compliance, lack of regulatory compliance, operations, enforcement actions, suitability for conducting its business, legal actions and/or warnings, brochures, policies and procedures, ordering, and delivery information company overviews, standard operating procedures, executive summaries, attachments A, B or others (relating to HIPAA, NECP policies and procedures, or other information).

RESPONSE TO REQUEST FOR PRODUCTION NO. 8:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and this request contains no time limitation. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties. ISSM further objects to this request on the ground that it is vague and ambiguous, including, but not limited to, the use of the phrase "attachments A, B or others."

REQUEST FOR PRODUCTION NO. 9:

Any and all documents and/or ESI reflecting or containing information obtained by, or communications received by, the Healthcare Provider, its employees and/or agents, concerning the fitness of any products purchased or obtained from NECP for their intended use, during the two-year period immediately preceding October 6, 2012, including but not limited to any environmental testing results, microbiology reports or certificates of analysis.

RESPONSE TO REQUEST FOR PRODUCTION NO. 9:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the time period of the request exceeds the time period for products covered by the recall, and this request includes within its scope information about products that have never been identified as contaminated. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 10:

Any and all documents and/or ESI reflecting or containing information obtained by, or sent to, the Healthcare Provider, its employees and/agents, from the Centers for Disease Control and Prevention, the Federal Food and Drug Administration, and/or any other Federal, state or local regulatory agency, concerning the fitness of any products manufactured, compounded or produced by NECP for their intended purpose.

RESPONSE TO REQUEST FOR PRODUCTION NO. 10:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and this request has no time limitation and includes within its scope information about products that have never been identified as contaminated. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, the CDC and/or the other agencies identified in the request. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 11:

Any and all documents and/or ESI reflecting or containing communications between the Healthcare Provider and any federal or state agency (including, but not limited to state licensing authorities, the Food and Drug Administration, and the Centers for Disease Control and Prevention) in connection with the procurement of products from any compounding pharmacy.

RESPONSE TO REQUEST FOR PRODUCTION NO. 11:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL and this request includes within its scope information about products that have never been identified as contaminated and about compounding pharmacies other than NECC that are not parties to the MDL. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, the CDC and/or the other agencies identified in the request. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 12:

Any and all documents and/or ESI reflecting or containing marketing information from NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

RESPONSE TO REQUEST FOR PRODUCTION NO. 12:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and this request contains no time limitation and includes within its scope information about products that have never been identified as contaminated. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 13:

Any and all documents and/or ESI reflecting or containing agreements, contracts and/or warranties between the Healthcare Provider and NECP, NECP's agents, or any sales company or person marketing, selling, or attempting to sell products on behalf of NECP.

RESPONSE TO REQUEST FOR PRODUCTION NO. 13:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and this request contains no time limitation includes

within its scope information about products that have never been identified as contaminated. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it is vague and ambiguous, including, without limitation, the use of the phrase “agreements, contracts and/or warranties,” such as, for example, whether that includes every purchase order or invoice in connection with any purchase from NECC. ISSM further objects to this request on the ground that it seeks documents that are available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 14:

Any and all documents and/or ESI reflecting or containing recall notices received by the Healthcare Provider pertaining to products produced by NECP, including without limitation of the foregoing, the date, time and manner of receipt of the recall notices, the specific person or persons within the Healthcare Provider who received the notice, and the substance of the notice.

RESPONSE TO REQUEST FOR PRODUCTION NO. 14:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL and none of ISSM’s patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks documents that are

available from, and more appropriately sought from, other persons or entities, including, without limitation, NECC and/or its trustee. ISSM further objects to this request on the ground that it seeks information that is cumulative and/or duplicative of information that is being sought from parties and/or other non-parties.

REQUEST FOR PRODUCTION NO. 15:

Any and all documents and/or ESI reflecting or containing communications made or issued by the Healthcare Provider, its employees and/or agents, in response to any recall notice regarding NECP products, including without limitation of the foregoing, the date, time and manner of transmission of the communication, the person(s) to which the communication was directed, and the person at the Healthcare Provider who made or delivered the communication.

RESPONSE TO REQUEST FOR PRODUCTION NO. 15:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the request does not contain any limitation as to the recipients of the communications and thus purports to include, for example, ISSM's communications with its counsel. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks information protected by HIPAA and/or state privacy and confidentiality laws, including, without limitation, because it includes within its scope communications with patients. ISSM further objects to this request on the ground that it seeks information that is protected from disclosure by the attorney-client privilege, work product

protection or other applicable protections, particularly to the extent it seeks “[a]ny and all documents and/or ESI reflecting or containing communications” concerning the topics in the request, which would purport to include privileged and protected information relating to ISSM’s response to the NECC recall and inquiries from government agencies.

REQUEST FOR PRODUCTION NO. 16:

Any and all documents regarding any investigation or inquiry the Healthcare Provider performed related to attempts by NECP to comply with United States Pharmacopeia —National Formulary, Chapter 797 (USP — NF General Chapter 797, entitled “Pharmaceutical Compounding — Sterile Preparations”).

RESPONSE TO REQUEST FOR PRODUCTION NO. 16:

ISSM objects to this request on the grounds that it is overbroad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL and none of ISSM’s patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave.

REQUEST FOR PRODUCTION NO. 17:

Any and all policies of insurance, including without limitation of the foregoing, professional liability, malpractice, products liability, general liability, and comprehensive or umbrella policies, issued to the Healthcare Provider and/or its principal officers and directors and/or any physician working for or on behalf of the Healthcare Provider, for the policy periods including calendar years 2011, 2012 and 2013.

RESPONSE TO REQUEST FOR PRODUCTION NO. 17:

ISSM objects to this request on the grounds that it is overbroad, vexatious, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the request includes within its scope information about insurance coverage unrelated to any coverage for the NECC matter. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks proprietary and confidential information of ISSM, which information would not adequately be protected by the Confidentiality Order to which ISSM never agreed and was never afforded an opportunity to provide input.

REQUEST FOR PRODUCTION NO. 18:

Articles of Incorporation and/or By-Laws applicable to the Healthcare Provider for calendar years 2011, 2012 and 2013.

RESPONSE TO REQUEST FOR PRODUCTION NO. 18:

ISSM objects to this request on the grounds that it is overbroad, vexatious, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the request includes within its scope organizational documents that pre-date and post-date the NECC matter. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave.

ISSM further objects to this request on the ground that it seeks proprietary and confidential information of ISSM, which information would not adequately be protected by the Confidentiality Order to which ISSM never agreed and was never afforded an opportunity to provide input.

REQUEST FOR PRODUCTION NO. 19:

Any and all documents and/or ESI reflecting or containing the names, addresses and positions (President, Vice-President, Director, etc.) within the Healthcare Provider of all officers and directors of the Healthcare Provider during the calendar years 2011, 2012 and 2013.

RESPONSE TO REQUEST FOR PRODUCTION NO. 19:

ISSM objects to this request on the grounds that it is overbroad, vexatious, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the request contains no temporal relationship to the NECC matter. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks proprietary and confidential information of ISSM, which information would not adequately be protected by the Confidentiality Order to which ISSM never agreed and was never afforded an opportunity to provide input.

REQUEST FOR PRODUCTION NO. 20:

Any and all documents showing the entities or individuals with an ownership interest in the Healthcare Provider.

RESPONSE TO REQUEST FOR PRODUCTION NO. 20:

ISSM objects to this request on the grounds that it is overbroad, vexatious, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the request contains no temporal relationship to the NECC matter. ISSM further objects to this request on the ground that it exceeds the limitations on non-party discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks proprietary and confidential information of ISSM, which information would not adequately be protected by the Confidentiality Order to which ISSM never agreed and was never afforded an opportunity to provide input.

REQUEST FOR PRODUCTION NO. 21:

Any and all organizational charts maintained by the Healthcare Provider and/or any documents listing directors, officers, employees, and/or agents of the Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider.

RESPONSE TO REQUEST FOR PRODUCTION NO. 21:

ISSM objects to this request on the grounds that it is overbroad, vexatious, and not reasonably calculated to lead to the discovery of admissible evidence, including, but not limited to, because neither ISSM nor any of its patients is a party to the MDL, none of ISSM's patients has had any adverse reaction to any products from NECC and the incubation period identified by the CDC has long expired, and the request contains no temporal relationship to the NECC matter. ISSM further objects to this request on the ground that it exceeds the limitations on non-party

discovery imposed by the Order Granting Leave. ISSM further objects to this request on the ground that it seeks proprietary and confidential information of ISSM, which information would not adequately be protected by the Confidentiality Order to which ISSM never agreed and was never afforded an opportunity to provide input.

Dated: New York, New York
July 24, 2013

GOLENBOCK EISEMAN ASSOR BELL
& PESKOE LLP

By: 

Martin S. Hyman
Matthew C. Daly

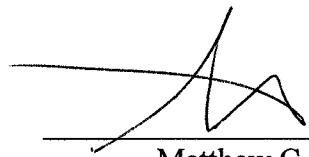
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*Attorneys for Non-Party Interventional
Spine & Sports Medicine, PC*

CERTIFICATE OF SERVICE

I, Matthew C. Daly, hereby certify that on July 24, 2013, a true and correct copy of the foregoing was submitted to the Court for service on all parties of record by virtue of the Court's electronic filing system and additionally was served on counsel for Plaintiffs' Steering Committee, Patrick T. Fennell, Esq., Crandall & Katt, 366 Elm Avenue, S.W., Roanoke, Virginia 24016, by United States mail.

Dated: July 24, 2013



Matthew C. Daly